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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2022-0132; FRL- 9411-12-OCSPP]

Certain New Chemicals; Receipt and Status Information for December 2022

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the *Federal Register* pertaining to submissions under TSCA section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 12/1/2022 to 12/31/2022.

DATES: Comments identified by the specific case number provided in this document must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2022-0132, through the *Federal eRulemaking Portal* at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Jim Rahai, Project Management and Operations Division (MC 7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8593; email address: rahai.jim@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 12/01/2022 to 12/31/2022. The Agency is providing notice of receipt of PMNs, SNUNs, and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices. This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, a chemical substance may be either an "existing" chemical substance or a "new" chemical substance. Any

chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a "new chemical substance," while a chemical substance that is listed on the TSCA Inventory is classified as an "existing chemical substance." (See TSCA section 3(11).) For more information about the TSCA Inventory please go to: https://www.epa.gov/tsca-inventory.

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN, or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for "test marketing" purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to:

https://www.epa.gov/chemicals-under-tsca.

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the *Federal Register* certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

- D. Does this action have any incremental economic impacts or paperwork burdens?

 No.
- E. What should I consider as I prepare my comments for EPA?
- 1. Submitting confidential business information (CBI). Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.
- 2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at https://www.epa.gov/dockets/commenting-epa-dockets.

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the *Federal Register* after providing notice of such changes to the public and an opportunity to comment (see the *Federal Register* of May 12, 1995 (60 FR 25798) (FRL-4942-7)). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received,

the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices. This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (*i.e.*, domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter "A" (e.g. P-18-1234A). The version column designates submissions in sequence as "1", "2", "3", etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that future version of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

Table I. – PMN/SNUN/MCANs Approved* from 12/1/2022 to 12/31/2022

Case No.	Version	Received	Manufacturer	Use	Chemical Substance
		Date			
P-18-	4	12/19/2022	CBI	(G) Primer	(G) Modified fat
0146A				paint binders	amines, polymers with
				for open non-	bisphenol A,
				dispersive uses	alkanolamines,

P-22-	4	12/01/2022	Materion	(G) This	epichlorohydrin, alkylamine and substituted isocyanato [isocyanatoalkylcarbo monocyle] (G) Metal Oxide
0002A			Advanced Chemicals	product is used for the manufacturing of electronic devices	Chloride
P-22- 0095A	2	12/05/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22- 0096A	2	12/05/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22- 0097A	2	12/05/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22- 0098A	2	12/05/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22- 0099A	2	12/05/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22- 0100A	2	12/05/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates
P-22- 0101A	3	12/05/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts
P-22- 0102A	3	12/05/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts

P-22-	3	12/05/2022	Locus	(G) Surfactant	(G) Glycolipids,
0103A		12/03/2022	Fermentation	for consumer,	sophorose-contg.,
010371			Solutions	industrial,	yeast-fermented, from
			Solutions	commercial	glycerides and
				applications	carbohydrates, salts
P-22-	3	12/05/2022	Locus		(G) Glycolipids,
0104A	3	12/03/2022	Fermentation	(G) Surfactant for consumer,	
0104A			Solutions	industrial,	sophorose-contg., yeast-fermented, from
			Solutions	1	,
				commercial	glycerides and
D 22	12	10/05/2022	Τ	applications	carbohydrates, salts
P-22-	3	12/05/2022	Locus	(G) Surfactant	(G) Glycolipids,
0105A			Fermentation	for consumer,	sophorose-contg.,
			Solutions	industrial,	yeast-fermented, from
				commercial	glycerides and
		1.7 (0.7 (0.0.7)	_	applications	carbohydrates, salts
P-22-	3	12/05/2022	Locus	(G) Surfactant	(G) Glycolipids,
0106A			Fermentation	for consumer,	sophorose-contg.,
			Solutions	industrial,	yeast-fermented, from
				commercial	glycerides and
				applications	carbohydrates, salts
P-22-	3	12/12/2022	CBI	(G) Resin for	(G)
0119A				packaging and	Polyhydroxyalkanoate
				Binding agent	
P-22-	3	12/12/2022	CBI	(G) Resin for	(G)
0120A				packaging,	Polyhydroxyalkanoate
				Binder	
				materials.	
P-23-	2	12/19/2022	CBI	(G) Fragrance	(G) Cysteine, cyclic
0009A				ingredient for	alkyl, ethyl ester
				use in laundry	
				applications.	
P-23-	5	12/12/2022	CBI	(S)	(G) [Polyalkyl-
0014A				Intermediate in	methylenepolyhydro-
				production of	polycyclic alkyl
				fragrance	acetate
P-23-	3	12/13/2022	CBI	(S)	(G) gelatin and
0028				Encapsulating	maltodextrin
				Shell Polymer	crosslinked with linear
				for Fragrance	and cyclic aliphatic
				Encapsulates	polyisocyanates
				for Industrial	
				or Household	
				Consumer	
				Products such	
				as Detergents	
				and Fabric	
				Softeners	
P-23-	2	12/07/2022	CBI	(G) Battery	(G) Cobalt metal
0029A		12/0//2022		Cathode	nickel oxide
002 <i>)</i> A				Manufacturing	meker oalde
D 22	2	12/12/2022	CDI		(C) April alleaver ather
P-23-		12/13/2022	CBI	(G) Isolated	(G) Aryl alkoxy ether

0035				intermediate	
P-23- 0036	1	11/30/2022	Elantas PDG, Inc.	(S) MF8044 Resin is an unsaturated polyester resin used in an electrical insulation coating. The coating is used to insulate electrical components in automobiles.	(S) Castor oil, polymer with dicyclopentadiene, maleic anhydride, 2-methyl-1,3-propanediol, 3a,4,7,7a-tetrahydro-2-(2-hydroxyethyl)-1H-isoindole-1,3(2H)-dione and triethylene glycol
P-23- 0037	1	12/01/2022	CBI	(G) Photoacid generator (PAG) for use in electronics industry	(G) Monoaromatic cyclic alkylene sulfonium fluoroalkyl sulfonic acid salt,
P-23- 0038	2	12/07/2022	Allnex, USA Inc.	(S) Crosslinker (hardener) for various water dilutable backbone binders (e.g. polyester resins, epoxy resins or acrylic resins) in order to obtain high chemical resistant protective layers for heat curing metal application.	(G) Formaldehyde, polymer with phenol, carboxyalkyl ethers, alkali salts, compds. with (dialkylamino)alkanol
P-23- 0039	2	12/19/2022	Evonik Corporation	(S) Surfactant in manual/hand dish detergent, surface cleaner, laundry detergent	(G) Rhamnolipids, modified pseudomonas- fermented, from dextrose, salts
P-23- 0040	2	12/19/2022	Evonik Corporation	(S) Surfactant in manual/hand dish detergent, surface cleaner, laundry detergent	(G) Rhamnolipids, modified pseudomonas- fermented, from dextrose, salts

P-23- 0041	1	12/09/2022	CHT USA Inc.	(G) Additive into consumer cleaning products, Industrial & Institutional Cleaners	(G) Siloxane & Silicone, alkyl amino polymer
P-23- 0042	1	12/12/2022	Clariant Corporation	(S) Intermediate for use in producing polymers.	(G) Oxirane, alkyl-, polymer with oxirane, monoethers with polyethylene glycol alkenyl ether
P-23- 0043	1	12/12/2022	Clariant Corporation	(S) Intermediate for use in producing polymers.	(G) Oxirane, alkyl-, polymer with oxirane, sulfate, ethers with polyethylene glycol alkenyl ether, salt
P-23- 0044	1	12/13/2022	CBI	(G) Photoacid generator (PAG) for use in electronics industry	(G) Monoaromatic cyclic alkylene sulfonium fluoroalkyl sulfonic acid salt,
P-23- 0046	1	12/16/2022	CBI	(G) Process aid for the fabrication of molded articles	(G) Siloxanes and Silicones, di-alkyl, hydroxy-terminated, polymers with substituted alkane and substituted silane
P-23- 0047	1	12/16/2022	CBI	(G) Additive in plating baths	(G) Heteromonocyclic, dialkyl amide, substituted alkyl salt
P-23- 0048	2	12/19/2022	Dynax Corporation	(G) Additive used in industrial and commercial applications	(G) Alkenoic acid, reaction products with polyalkenimine, polymercapto alkanolester and C6-fluoro haloalkane, compds. with alkanolamine
P-23- 0049	1	12/21/2022	CBI	(G) Photolithograp hy	(G) Sulfonium, tricarbocyclic-, 2-aryl-polyfluoropolyhydro-alkano - heteropolycycle-alkanesulfonate (1:1), polymer with heteroatom substituted aryl and carbomonocyclic 2-alkyl-2-alkanoate, di-Me 2,2-(1,2-

					diazenediyl)bis[2- methylpropanoate]- initiated
P-23- 0050	1	12/23/2022	SHIN-ETSU Microsi	(G) Contained use for microlithograp hy for electronic device manufacturing	(G) Substitutedheterocycli c onium compound, salt with heteropolysubstituteda lkyl substitutedtricycloalka necarboxylate (1:1), polymer with 3- ethenylphenol and heterosubstitutedarom aticalkyl 2-methyl-2- propenoate, di-Me 2,2'-(1,2- diazenediyl)bis[2- methylpropanoate]- initiated

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs that have passed an initial screening by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (e.g., amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

Table II. – NOCs Approved* from 12/1/2022 to 12/31/2022

Case	Received	Commencement	If	Chemical Substance
No.	Date	Date	Amendment,	
			Type of	
			Amendment	
P-11-	12/06/2022	08/29/2022	Amended	(G) Propane, fluoro-substituted-
0224A			generic	3-(1,1,2,2-tetrafluoroethoxy)-
			chemical	
			name	
P-21-	11/30/2022	11/28/2022	N	(G) Ethyl 4-alkyl-2-
0019				oxocycloalkanecarboxylate

^{*}The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission.

information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

Table III. – Test Information Received from 12/1/2022 to 12/31/2022

Case	Received	Type of Test	Chemical Substance
No.	Date	Information	
P-13-	12/05/2022	Revised Test Data	(G) Perfluoroacrylate polymer
0021		Validation Study	
P-14-	11/30/2022	Polychlorinated	(G) Plastics, wastes, pyrolyzed, bulk
0712		Dibenzodioxins and	pyrolysate
		Polychlorinated	
		dibenzofurans Testing	
P-14-	12/19/2022	Testing Notice	(G) Plastics, wastes, pyrolyzed, bulk
0712			pyrolysate
P-15-	12/21/2022	90-Day Inhalation	(G) Rare earth doped zirconium oxide
0443		Toxicity Testing (OECD	
		Test Guideline 413)	
P-22-	12/14/2022	Water Solubility:	(G) Substituted heterocyclic onium
0129		Column Elution	compound, salt with
		Method; Shake Flask	heteropolysubstitutedalkyl
		Method (OECD Test	substitutedtricycloalkane carboxylate
		Guideline 105)	(1:1), polymer with 1-alkenyl-4-
			[(alkylcycloalkyl)oxy]carbomonocycle, 5-
			ethyloctahydro-4,7-methano-1h-inden-5-
			yl 2-methyl-2-propenoate, hexahydro-5-
			oxo-2,6-methanofuro[3,2-b]furan-3-yl 2-
			methyl-2-propenoate and 4-
			hydroxyphenyl 2-methyl-2-propenoate
P-23-	12/06/2022	Bacterial Reverse	(G) Phenol, polyalkylcarbo bis-, polymer
0030		Mutation Test (OECD	with 2-
		Test Guideline 471)	carbomonocyclichaloheteromonocycle,
			bis[(alkenylcarbomonocyclic)alkyl] ether

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under FOR FURTHER INFORMATION CONTACT to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 et seq.

Dated: January 12, 2023.

Pamela Myrick,

Director, Project Management and Operations Division, Office of Pollution Prevention and Toxics.

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